

**REMARKS**

**Restriction Requirement**

The Examiner has restricted the invention under 35 U.S.C. §121 into the following groups:

- I. Claims 1-6, 8-18 drawn to a tubular prosthesis.
- II. Claim 7 drawn to a layer of fabric material.

The Office Action further requires the application to be restricted to one of the following subgroups: Figure 3A, Figure 3B, Figure 3C, Figure 4A, Figures 5A or Figure 7.

Applicant confirms the provisional election made by telephone conference on January 8, 2002, to prosecute Group I and subgroup A, but respectfully traverses the restriction requirement in view of the remarks below.

According to M.P.E.P. 803, restriction is proper only if the claims are able to support separate patents and they are either independent or distinct (806.04-806.05(i)). Section 803 also states that even if distinct or independent claims exist, examination on the merits is required providing the search can be made without serious burden.

Applicants respectfully request that the requirement of election among the various Groups and subgroups be withdrawn.

**Section 102 Rejections**

Claims 1-3, 5, 6, 8, 11-13 have been rejected as being anticipated under 35 U.S.C. §102 by U.S. Patent No. 4,331,697 (Kudo). This rejection is traversed on the basis that Kudo fails to teach each and every element of the Applicant's claims. Specifically, Kudo fails to disclose, teach or suggest a radiation resistant and hydrolytically stable implantable fabric made from a naphthalene derivative.

Kudo is solely directed at chemically building a heparin derivative to the polymeric surface of a medical device. The polymeric surface of the device must have functional groups available to react with the heparin derivative. The result is a graft copolymer formed by the reaction of heparin with the polymeric surface.

As noted by the Examiner, polyethylene-2, 6-naphthalate is recited by Kudo as being a useful polyester in the formation of a heparin copolymer because it possess the requisite carboxylic functionality for forming the copolymer with the heparin derivative. However, contrary to the Examiner's Office Action, Kudo's polymer material is intentionally different from that claimed by Applicant.

Kudo's copolymerization reaction changes the surface of the device to that of a different chemical structure, and by doing so fulfills the intent and purpose of his teachings for an antithrombogenic polymer. Kudo's entire invention is directed toward achieving a different polymeric surface through copolymerization. Thus, the original polyethylene-2, 6-naphthalene polymeric surface has been changed to a chemically different copolymer. The modification of the surface to form a new copolymer provides no indication that a radiation resistant and hydrolytically stable biocompatible fabric could or would result, and in fact the presence of additional chemical linkages now incorporated into the fabric provides one of ordinary skill in the art with a host of questions as to the effect in stability and radiation resistance such chemical changes will have. This is a clear teaching away from the usefulness of polyesters, and in particular polyethylene-2, 6-naphthalate, in the absence of such a co-reaction with the heparin derivative. Kudo fails to suggest that polyethylene-2, 6-naphthalate has any usefulness as a medical device beyond its ability to react to form a copolymer. Moreover, Kudo fails to disclose the use of polyethylene-2, 6-naphthalate without the formation of such a copolymer with heparin and as such fails as an anticipatory reference under Section 102.

### **Section 103 Rejections**

Claims 4, 9, 10, 14-17 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Kudo in view of U.S. 5,443,499 (Schmitt). This rejection is traversed on the basis that Kudo and Schmitt individually or in combination fail to teach or suggest the present invention.

Applicants' prior comments with respect to Kudo equally apply here. Kudo fails to teach or suggest that polyethylene-2, 6-naphthalate has any usefulness as a medical device beyond its ability to react to form a copolymer. In fact, Kudo teaches away from the use of polyethylene-2, 6-naphthalate in absence of a co-reaction with the heparin derivative and is entirely silent as to other naphthalene dicarboxylate derivatives set forth in Applicant's claims.

Schmitt is merely cited for its alleged teaching regarding a braided tubular prosthesis for use in blood vessels. The Examiner further alleges that Schmitt teaches a prosthesis that has 115 denier and 100 filaments which could be implanted along with a stent. This disclosure adds nothing to the Kudo disclosure which renders Applicants claims obvious. Thus, Schmitt fails to remedy the deficiencies of Kudo.

Thus, Schmitt and Kudo, individually or in combination, fail to teach or suggest the present invention as set forth in claims 4, 9, 10, 14-17. Therefore, reconsideration and withdrawal of the rejection of claims 4, 9, 10, 14-17 are respectfully requested.

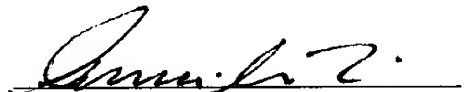
Claims 4, 14-16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Kudo in view of EP461791 (Barone). The Examiner alleges Barone teaches graft materials for use in vascular bodies can be of woven construction. The Examiner further alleges that Barone teaches the graft is to be used with a support structure in the form of a stent. The Examiner has combined Barone with Kudo, alleging such a combination would lead one of ordinary skill in the art to the present invention. The rejection is respectfully traversed on the basis that the Examiner has failed to set forth a *prima facie* case of obviousness.

Applicant: Moroni  
Serial No: 09/577,790  
Docket No: 498-206  
Page 6

Applicant's prior comments with respect to Kudo equally apply here, but will not be repeated for the sake of brevity. Barone adds no teaching or suggestion with respect to providing a radiation resistant and hydrolytically stable biocompatible fabric made from a plurality of polymeric filaments including naphthalene dicarboxylate derivatives. Barone therefore adds nothing to cure the deficiencies of Kudo. The use of Barone in combination with Kudo therefore fails to teach or suggest an implantable prosthesis as claimed. Withdrawal of the §103 rejection over Kudo in view of Barone is respectfully requested.

In view of the above remarks, it is respectfully submitted that the claims are patentable over the art and allowable in form. Early allowance is respectfully solicited. Should the Examiner have any questions, please do not hesitate to contact the undersigned.

Respectfully submitted,

  
Anna-Lisa Gallo  
Registration No.: 50,279  
Attorney for Applicant(s)

HOFFMANN & BARON, LLP  
6900 Jericho Turnpike  
Syosset, New York 11791  
(973) 331-1700